DEC 2 0 2000

510(k) Summary for Heartstream FR2 AED

K003565

Date Summary Prepared

November 17, 2000

Submitter's Name and Address

Agilent Technologies
Heartstream Operation
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Contact Person

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Device Name

Proprietary Name:	Heartstream FR2 AED
Common Name:	Semi-automatic external defibrillator
Classification Names:	Low-Energy Defibrillator, Arrhythmia Detector and Alarm

Predicate Devices

The legally marketed device to which Agilent Technologies claims equivalence for the Heartstream FR2 AED is the Heartstream ForeRunner AED.

The design of the Heartstream FR2 AED is substantially equivalent in safety and performance to the device named above.

Device Description

The Heartstream FR2 is a semi-automatic external defibrillator available in two models, including one with ECG display and manual shock capability. Features include extensive self-testing, impedance-compensating biphasic truncated exponential waveform, multi-parameter Patient Analysis System (PAS), and human factors designed to facilitate use by lay responders.

A lithium manganese dioxide battery powers the FR2 with a typical capacity of 300 shocks or 12 hours of operating time.

The Heartstream FR2 automatically analyzes the ECG - there is no delay in analysis by requiring a responder to activate a "press to analyze" button. Except for specific programmed periods when a responder needs to deliver uninterrupted CPR, the FR2 continuously analyzes the ECG and alerts the responder when the ECG changes to a possible shockable rhythm. Analysis continues even after the FR2 advises a shock and arms - if the ECG spontaneously converts to a non-shockable rhythm prior to a

responder pressing the shock button, the FR2 disarms to prevent inappropriate shock delivery.

If significant artifact is detected in the ECG, Heartstream's PAS suspends further analysis until reliable data is available. This artifact detection method provides an additional margin of safety when adverse conditions are present.

When a shockable rhythm is detected, the FR2 directs the responder to press the shock button to deliver a single energy (150 Joule) biphasic shock to the patient.

Event and incident data can be recorded during FR2 use with a data card having a recording capacity of four hours of event and ECG data (or thirty minutes with voice recording).

The FR2 has a Training and Administration Pack that is used for device training and for customizing FR2 set-up options. Use of the Training and Administration Pack converts the FR2 to a training device with ten training "scripts" that simulate different SCA scenarios. Use of the Pack for administration purposes allows authorized personnel to program several parameters of FR2 operation and allow for compliance with local CPR-AED protocols.

The FR2 also has an infrared communication port to facilitate communication of setup parameters.

Intended Use

The Heartstream FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, or advanced life support, or other physician-authorized emergency medical response.

The Heartstream FR2 is indicated for use on victims of sudden cardiac arrest exhibiting the following signs:

- Unresponsiveness
- Absence of breathing

Comparison of Technology Characteristics

The Heartstream FR2 AED employs the same fundamental scientific technology as the Heartstream ForeRunner AED.

Data Used in Determination of Substantial Equivalence

The Heartstream FR2 employs the same technologies as the predicate device used for comparison. The FR2 acquires and analyzes ECG signals, and utilizes the same shock advisory criteria like the predicate. The waveform used for defibrillation shocks is the same as the predicate's, as are the primary voice prompts, battery type and chemistry. Because this is a Special 510(k), a statement is provided to certify that the FR2 AED was developed in accordance with design control requirements.

The objective of Heartstream was to determine whether any of the FR2's revised features or change in labeling (to eliminate the initial pulse check prior to AED use) raised any questions regarding the effectiveness or safety of the device. The effectiveness of emergency response could potentially increase as a result of the labeling change; however, the effectiveness of the therapy itself does not change. Heartstream did identify one question regarding safety. This question results from the expectation that the FR2 AED without the initial pulse check requirement will be applied to a greater number of pulsatile patients than the ForeRunner AED.

We provide data that address the question of safety by demonstrating the specificity (or ability to accurately detect rhythms for which a shock is not indicated) of the FR2's Patient Analysis System (PAS). The PAS analyzes the patient's heart rhythm and makes a determination of whether a shock is indicated. To support this claim, Heartstream provides data from bench-testing, post-market surveillance, clinical data, and an analysis of customer reports in the Heartstream complaint tracking system.

The Heartstream Patient Analysis System (PAS)

With the elimination of the initial pulse check, the FR2 AED will likely be exposed to more rhythms that are associated with a pulse. In order to ensure patient safety, the Heartstream Patient Analysis System (PAS) has a robust, multi-parameter design that provides a high degree of specificity, or ability to accurately detect rhythms for which a shock is not indicated.

The Heartstream PAS is designed to:

- Exhibit high specificity for perfusing rhythms
- Be conservative with rhythms with uncertain perfusion status (intermediate rhythms)

The American Heart Association (AHA) defines intermediate rhythms as "...rhythms for which the benefits of defibrillation are limited or uncertain." - in practical terms, these rhythms may or may not be associated with a pulse. Because of the uncertain association of a pulse, clinicians disagree about how these rhythms are best treated. The therapeutic benefit of a shock is uncertain, and in addition, the victim may potentially be exposed to some risk if a shock is delivered. The risk that results from eliminating the pulse check prior to AED use is that the presence of a pulse in patients with intermediate rhythms can not be determined by analysis of the ECG alone. Therefore, it is imperative that intermediate rhythms be treated conservatively, i.e., not shocked, in order to assure patient safety.

Heartstream's treatment of intermediate rhythms is conservative, tending to result in no-shock decisions. If the intermediate rhythm is truly associated with sudden cardiac arrest, it will soon show shockable characteristics. After the rhythm shows shockable characteristics, the FR2 AED automatically detects the change and advises a shock if the rhythm is confirmed as shockable.

The PAS characterizes an ECG in terms of four rhythm characteristics: rate of complex occurrence, morphological stability of complexes, complex conduction speed, and complex amplitude. These measures are assessed concurrently to make each shock / no shock determination.

The Heartstream PAS demonstrated 100% specificity in bench-testing:

SPECIFICITY

Rhythm Class	AHA Performance Goal	Actual Performance	Pass / Fail
NSR	99%	100%	Pass
All Other Non-Shockable Rhythms	95%	100%	Pass
Asystole	95%	100%	Pass

Post-Market Surveillance

In the most extensive post-market surveillance ever published on AED sensitivity and specificity, Heartstream's PAS demonstrated 100% sensitivity and specificity.[i]

The protocol for Heartstream's post-market surveillance was submitted to the FDA in April 1996 (reference reference 510(k) #K955628). In the preparation of the protocol, Heartstream consulted the FDA document "Guidance to Manufacturers on the Development of Required Postmarket Surveillance Study Protocols Under Section 522 (a)(1) of the Federal Food, Drug and Cosmetic Act", draft.

The results of the post-market surveillance were published in 1998. Two hundred and eighty-six (286) consecutive AED uses were analyzed, 100 uses from sudden cardiac arrest (SCA) victims with ventricular fibrillation (VF) as their initial rhythm. All 286 patients were correctly identified by the PAS algorithm as requiring a shock or not (100% sensitivity for the 100 VF patients, 100% specificity for the 186 patients not presenting in VF).

It is important to note that over 44% of the rescuers in this post-market surveillance were laypersons - police officers, flight attendants, and non-Emergency Medical Technician (EMT) emergency responders. In addition, approximately ten percent of the AED uses were in environments that increase the difficulty of pulse assessment (airplanes, cars, train, boat).

Clinical Data

Two abstracts in the peer-reviewed publication *Pace* examine the sensitivity and specificity of the Heartstream PAS in the compromising environment of an aircraft.[ii,iii] In over 200 uses of the Heartstream AED, the PAS algorithm had 100% sensitivity and specificity.

Review of Customer Reports Related To PAS Specificity

Heartstream maintains a complaint tracking system in accordance with quality system requirements. All records in the system for the period of November, 1996, when the first Heartstream AED was shipped, to June 5, 2000, were reviewed. No customer reports

were identified that had any negative implications for the Heartstream PAS to function appropriately with a change in indications to eliminate the initial pulse check.

Conclusion

The Heartstream FR2 with modified labeling for use is equivalent to the ForeRunner AED currently marketed. The question identified regarding safety of the device to appropriately not advise shocks for patients with a pulse is fully addressed by the design of the Heartstream Patient Analysis System (PAS), as demonstrated by the excellent specificity performance in bench testing, field testing, and use history.

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[i] Gliner BE, et al. Treatment of out-of hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomedical Instrumentation & Technology*, November/December 1998, 631-643.

[ii] Page RL, et al. Automatic external defibrillator use on a domestic airline: results from the first 200 cases. *Pace*, April 2000;23(4)(Part II):606(216, abstract).

[iii] Kowal RC, et al. Ventricular fibrillation treated with an aircraft automatic external defibrillator: characterization of episodes and survival. *Pace*, April 2000;23(4)(Part II):744(768, abstract).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Ms. Gretchen Solberg
Agilent Technologies, Inc.
Heartstream Operation
2401 Fourth Avenue, Suite 500
Seattle, WA 98121-1436

Re: K003565
Heartstream FR2 AED
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: November 17, 2000
Received: November 20, 2000

Dear Ms. Solberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To be assigned K003565

Device Name: Agilent Technologies Heartstream FR2 Semi-Automatic External Defibrillator (AED)

Indications For Use: The Heartstream FR2 is indicated for use on victims of sudden cardiac arrest exhibiting the following signs:

- Unresponsiveness
- Absence of breathing

The Heartstream FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, advanced life support, or other physician-authorized emergency medical response.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003565